



March 3, 2023

New Formulation of ROTARIX®

Dear VFC Providers,

On November 4, 2022, the FDA approved a new formulation of ROTARIX®. This new presentation (NDC 58160-0740-21, an oral dosing applicator only presentation) is fully liquid and therefore does not require reconstitution or dilution. It will replace the current lyophilized formulation (NDC 58160-0854-52, a vial and oral dosing applicator presentation), which requires reconstitution with the diluent before administration. The old formulation will be removed, and the new formulation will be added to our VFC Order form.

A single dose of the new liquid formulation is 1.5 mL (the old lyophilized formulation dose is 1 mL). Both formulations contain the same live, attenuated rotavirus strain and are manufactured using a similar process. Clinical trials comparing the two formulations showed safety profiles that were generally similar. Compared to the old formulation, the new formulation contains disodium adipate, and no longer contains sorbitol or phenol red. Since the new formulation does not require reconstitution or dilution, please review the [“Oral Dosing Applicator Only Presentation”](#) section in the Full Prescribing Information for details on how to prepare and administer the vaccine. See Sections 2, 3, 6.1, 11, and 14 of the [Full Prescribing Information](#) for further details.

Please continue to maintain best practices by rotating your inventory and using your current inventory of ROTARIX® before ordering and administering the new formulation of ROTARIX®. Inventory should be kept separate, and diluent must only be used with the old lyophilized formulation.

Thank you,

VACCINES for CHILDREN
CALIFORNIA



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